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EXAMINER	
GUPTA, A	
ART UNIT	PAPER NUMBER
1654	5

This is a communication from the examiner in charge of your application. DATE MAILED: 06/05/98
COMMISSIONER OF PATENTS AND TRADEMARKS

■ This application has been examined ■ Responsive to communication filed on ___ □ This action is made final.

A shortened statutory period for response to this action is set to expire 3 MONTHS from the date of this letter.
Failure to respond within the time period will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENTS ARE PART OF THIS ACTION:

1. ■ Notice of References Cited by Examiner, PTO-892.
2. □ Notice re Patent Drawing, PTO-948.
3. ■ Notice of Art Cited by Applicant, PTO-1449
4. □ Notice of Informal Patent Application, Form PTO-152.
5. □ Information on How to Effect Drawing Changes, PTO-1474.
6. □ _____

Part II SUMMARY OF ACTION

1. ■ Claims 1-13 are pending in the application.
   Of the above claims, 11-12 are withdrawn from consideration.
2. ■ Claims 1-3, 7-10, 13 have been cancelled.
3. □ Claims ___ are allowed.
4. ■ Claims 4-6 are rejected.
5. □ Claims ___ are objected to.
6. □ Claims ___ are subject to restriction or election requirement.
7. □ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. □ Formal drawings are required in response to this Office action.
9. □ The corrected or substitute drawings have been received on ___. Under 37 C.F.R. 1.84 these drawings are □ acceptable. □ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. □ The proposed additional or substitute sheet(s) of drawings, filed on ___ has (have) been □ approved by the examiner. □ disapproved by the examiner (see explanation).
11. □ The proposed drawing correction, filed on ___ has been □ approved. □ disapproved (see explanation).
12. □ Acknowledgment is made of the claim for priority under 35 USC 119. The certified copy has □ been received □ not been received □ been filed in parent application, serial no. ___; filed on ___.
13. □ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. □ Other

EXAMINER'S ACTION

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 4-6, drawn to the therapeutic use of Relaxin-Like Factor, classified in class 514, subclass 2.

II. Claim 11-12, drawn to a method of using relaxin like factor in a binding assay , classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

The methods of all three Groups are distinct in that the method involved for therapeutic use do not suggest binding assay of receptor mapping since the method is different. For therapeutic use, parameters such as to dosage and manner of administration must be established for in-vivo use, which are needed for in-vitro testing of Group II.

Because these inventions are distinct for the reasons given above and have acquired a separate status because of their recognized divergent subject matter and the search required for Group I is not required for Group II, and , restriction for examination purposes as indicated is proper.

During a telephone conversation with Kathaleen Fuller on 06-03-98 a provisional election was made with traverse to prosecute the invention of Group I, claims 4-6. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Claim Rejections - 35 USC § 112
First Paragraph

3 Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The nature of the invention is drawn to a method of treating various diseases by the administration of Relaxin like Polypeptides. The diseases include cardiovascular diseases, neurological or neurodegenerative disease, sinus bradycardia, depression, hair loss, or diseases related to uncontrolled or abnormal collagen or fibronectin formation.

(2) The state of the prior art

The art does not teach the specific relaxin like peptides claimed are effective in treating any of the disorders claimed. However, the art has recognized the effectiveness of relaxin in certain diseases, such as acute heart failure for cardiovascular disorders and the effectiveness of relaxin increasing heart rate associated with sinus bradycardia.

(3) The relative skill of those in the art

The relative skill of the those in the art is high.

(4) The predictability or unpredictability of the art

The true fact of the state of the art in peptide chemistry is expressed succinctly in the Rudinger article (see the conclusions in particular). "The significance of particular amino acids or sequences for different aspects of biological activity cannot be predicted a priori but must be determined from the case to case by painstaking experimental study."

For certain disorders, as encompassed by the claims, such as neurological disorders the art has recognized the attempts to treat nervous system degenerative diseases by using neurotrophic factors such as CNTF., BDNF, and NGF etc. For most of these neurotrophic factors, although the initial experimentation was encouraging, the clinical trials demonstrated the trophic factors to be ineffective due to the side. Yuen et al. reviewed the effectiveness, at the clinical stage, for many of the neurotrophic factors in the treatment of neuro-degenerative diseases.

(5) The breadth of the claims

The breath of the claims are broad since the claims do not clearly specify in what manner many of the disorders claimed are treated. For example, how are neurodegenrative disorders to treated, does treatment involve regeneration of cells or an improvement in motor skill for diseases such ALS.

(6) The amount of direction or guidance presented and (7) The presence or absence of working examples

The specification has not provided ample guidance as to the manner in which each disorder is to be treated or if truncated relaxin like factor would be effective in all of the disorders claimed. The extent of guidance provided in the specification is that the native peptide "Relaxin have been implicated consequently in the treatment and diagnosis of various diseases." Moreover, the specification only makes a suggestion in the treatment of all the disorders claimed without providing ample support as how and in what manner the disorders are treated. The specification is void of any working examples that would demonstrate beyond mere arguments that Relaxin Like peptides treat a specific disease in a specific manner. Guidance is necessary due to the fact that for certain disorders, known treatment methods have failed. For example, for neurodegenerative disorders such as ALS or Alzheimer's known compounds have been ineffective (see [redacted] Yuen et al).

Moreover, the claims also allow for the truncation of the peptides that are used to treat the disorders claimed. As stated by the Rudinger reference, "The significance of particular amino acids or sequences for different aspects of biological activity cannot be predicted a priori but must be determined from the case to case by painstaking experimental study." Moreover, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) (contrasting mechanical and electrical

elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." The article "Broader than the Disclosure in Chemical Cases," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail. Again the specification is void of any examples that would demonstrate that truncation of the peptide does not alter the activity of the peptides and thus are still useful in treating the claimed disorders.

(8) The quantity of experimentation necessary

The claims encompass many cardiovascular diseases and many different neurological disorders. Since applicants have not provided any guidance as to a specific condition to be treated for many of the disorders claimed, one of ordinary skill would burdened with undo experimentation to determine to what disorders the relaxin like polypeptide would be most effective in and conditions to treat. Even, for the specific disorders claimed one still would be burdened with undo experimentation to determine in what manner the conditions is to be treated. Moreover, the claims also allow for the use of truncated peptides of Relaxin like Polypeptides. However, since the significance of particular amino acids or sequences for different aspects of biological activity cannot be predicted a priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine the all of the peptide analogues would not affect the property of the peptide.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (703) 308-0254. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta

CECILIA J. TSANG
SUPERVISORY PATENT EXAMINER
GROUP 1800